

1FW

I hereby certify that this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 22 day of September, 2005.

By

Erica L. Smith
(Signature of person mailing)

Erica L. Smith

(Typed or printed name of person)

Patent Application
Docket No. PC25512A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
DAVID A. GRIFFITH

Serial No. 10/763,105
Filed on January 21, 2004

For: CANNABINOID RECEPTOR
LIGANDS AND USES THEREOF

Group Art Unit: 1624

Examiner: BALASUBRAMANIAN,
VENKATARAMAN

**AMENDMENT IN RESPONSE
TO A RESTRICTION REQUIREMENT**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

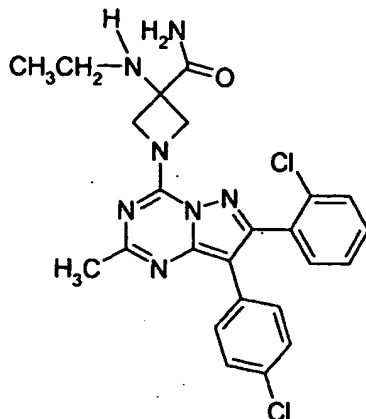
This amendment is being filed in response to a written restriction requirement mailed on August 26, 2005. Applicant hereby elects the claims of Group I (Claims 1-36, 56-80 and 97 drawn to a genus of the Formula I compound wherein R⁴ is a group of Formula IA and composition classified in class 544, subclasses 211 and others, class 514, subclasses 241 and others depending upon the preferred embodiment of Formula IA), with traverse. Applicant provisionally elects 1-[7-(2-Chloro-phenyl)-8-(4-chloro-phenyl)-2-methyl-pyrazolo[1,5-a][1,3,5]triazin-4-yl]-3-ethylamino-azetidine-3-carboxylic acid amide as the elected specie upon which the Examiner can initiate the examination of the elected claims. Applicants hereby reserve the right of rejoinder of any withdrawn claims in accordance with the provisions of MPEP §821.04.

Amendments begin on Page 2.

Remarks begin on Page 33.

Remarks

Claims 1-119 are pending in the application. Applicant respectfully traverses Examiner's restriction requirement in part. In compliance with the restriction request, Applicant elects the Group I claims with traverse. Applicant provisionally elects the following specie having the following structure



and chemical name, 1-[7-(2-Chloro-phenyl)-8-(4-chloro-phenyl)-2-methyl-pyrazolo[1,5-a][1,3,5]triazin-4-yl]-3-ethylamino-azetidine-3-carboxylic acid amide, as the elected specie upon which the Examiner can initiate the examination of the elected claims. The provisionally elected specie falls within the scope of all pending claims as amended by this amendment. The specie is specifically claimed in Claims 19 and 20, and new Claims 120 and 121.

Applicant would like to point out that some of the Group VI claims may be rejoined in accordance with the provisions of MPEP §821.04. Examiner's Group VI claims contain a mixture of different types of claims including (i) compositions comprising a combination of active ingredients including compounds of the present invention, (ii) methods of use for the compounds of the present invention or a pharmaceutical composition thereof, and (iii) methods of use for combinations with the compounds of the present invention.

In response to part of the Group VI restriction requirement, Applicants have cancelled the subject matter directed to the pharmaceutical compositions comprising a combination of active ingredients (Claims 98-100) and methods of using a combination of active ingredients (Claims 103-105, 109-111, and 113-117), without waiver or prejudice and without admission of anticipation or obviousness. Applicants reserve the right to file divisional applications to capture the cancelled restricted subject matter.

However, Applicants respectfully disagree with Examiner's restriction with respect to Claims 101, 106, 107, 108 and 112. Claim 101 and dependent Claims 106 and 107 are

directly linked to the compounds of Claim 1. Similarly, the method Claim 108 and dependent Claim 112 are directly linked to the composition Claim 97. Claims 101 and 108 have been amended to include all the limitations of the Group I compound and pharmaceutical composition claims, Claims 1 and 97, respectively; therefore, there would be no added burden on the Examiner to consider the pending method of use claims along with the compounds of Claim 1. Even though the method of use claims may be independent and distinct, these claims would be subject to rejoinder when the compounds of Claim 1 are found allowable. (see, MPEP 821.04).

Claim 1 has been amended to correspond to the restriction requirement by removing the non-elected groups where R^4 is a group of Formula IB. Formula IC and an amino group (iii).

Claims 37-55, 81-96, 98-100, 103-105, 109-111 and 113-119 have been cancelled as being directed to non-elected subject matter.

Claim 57 has been cancelled since it would not further limit the amended Claim 56 from which it depends. Similarly, Claim 102 was cancelled since it would not further limit the amended withdrawn Claim 101 from which it depends.

Claim 58 has been amended to provide proper dependency.

Withdrawn Claims 106 and 112 have been amended to provide proper dependency and to limit the claims to the elected subject matter corresponding to the Group I claims.

Support for new Claims 120 and 121 may be found in Example 2 (Compound No. 2A-1 and corresponding salts) of the specification on pages 101-104.

Respectfully Submitted:

Date: September 2, 2005

Arlene K. Musser
Arlene K. Musser
Attorney for Applicants
Registration No. 37,895

Pfizer Inc.
Patent Department, Box 8260-1611
Eastern Point Road
Groton, Connecticut 06340
(860) 715-0871



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,105	01/21/2004	David A. Griffith	PC25512A	7434

28523 7590 08/26/2005

PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT	PAPER NUMBER
----------	--------------

1624

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/763,105	Applicant(s) GRIFFITH, DAVID A.	
	Examiner Venkataraman Balasubramanian	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-119 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-119 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

58

DETAILED ACTION

Claims 1-119 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-36, 56-80 and 97 drawn to a genus of compound of formula I, wherein R^4 is a group of Formula IA and composition classified in class 544, subclasses 211 and others, class 514, subclasses 241 and others depending upon the preferred embodiment of Formula IA. If this group elected, a suitable combination of X, Y and Z should also be elected.
- II. Claims 1, 36-43, 56, 81-85 and 97 drawn to a genus of compound of formula I, wherein R^4 is a group of Formula IB, and composition, classified in class 544, subclasses 219 and others, class 514, subclasses 241 and others depending upon the preferred embodiment of Formula IB.. If this group elected, a suitable combination of X, Y and Z should also be elected.
- III. Claims 1, 44-56, 86-89 and 97 drawn to a genus of compound of formula I, wherein R^4 is a group of formula IC, i.e., choice ii, and composition classified in class 544, subclass 215 and others, class 514, subclasses 241 and others.
- IV. Claims 1, 56, 90-92 and 97 drawn to a genus of compound of formula I, wherein R^4 is choice iii, and composition, classified in class 544, subclass 218, class 514, subclass 241.

V. Claims 56, 93-95 and 97 drawn to a genus of compound of formula I, wherein R^4 is choice iv. and composition, classified in class 544, subclass 180, class 514, subclass 241.

VI. Claims 98-117 drawn to a complex pharmaceutical composition of genus of compound of formula I, and various method of use, classified in class 514, subclasses 241 and others depending upon the preferred embodiment of other active ingredients.

If this Group is elected applicant should also elect a specific R^4 group for examination.

VII. Claims 118 and 119, drawn to several intermediate compounds of formula Id, Ie, If, 2a, 2b, II-a and II-b, classified in classes 544, 546, subclasses various depending upon the preferred embodiment.

If this group is elected applicants should also elect a specific intermediate and a specific R^4 group for examination.

The inventions are distinct, each from the other because of the following reasons:

As per MPEP § 803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent or distinct as claimed and

(B) There must be a serious burden on the examiner if restriction is required.

Invention I, II, III, IV and V are independent and distinct from each other because they are directed to structurally dissimilar compounds distinct R^4 choices that lack common core, namely, **Formula IA** with various ring size and varying hetero atom

versus **Formula IB** with various ring size and varying hetero atom versus **Formula IC** with various hetero rings and other choices versus **choice iii** versus **choice iv** core groups. Consequently, the groups have different classifications and require separate prior art searches. They can be made and used independently. Art which may render obvious or anticipate one of the groups would not necessarily do the same for the other group. For example prior art cited in the International Search Report may not be applicable to all the above groups. In addition, prior art compounds excluded by a proviso in instant claims to obviate a rejection of compounds wherein R^4 is choice iii, may not be now applicable to entire invention. Each can support a patent as the compounds of each group are capable of being utilized alone not in combination with other members listed in the Markush group.

In addition, it is necessary to classify and search all the controlling cores generically embraced in Group I, II, III, IV and V along with various choices of heterocyclic ring embraced in Ar groups. Such a search of all controlling cores would be a serious search burden.

Group I-V and VI are related as product and the use of the product. In the instant case the product can be used for treating more than one disease and product other than those embraced in the instant claims including those excluded by the proviso can be used to treat diseases. Hence, Group I-V and VI are independent and distinct and require separate search for patentability which would be a serious search burden.

Inventions I-V and VII are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this

relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as pharmaceutical agents as well as making compounds with different scope as evident from scope of R4 of instant claim and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants.

This application contains claims directed to the following patentably distinct species of the claimed invention such as pyrazolotriazines with variety of R⁴ substituents. See claims

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-53 are generic.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In view of distinct nature of each of the invention, the restriction is set forth in writing.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571)

Art Unit: 1624

272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Acting Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is (571) 272-0661.

The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).


Venkataraman Balasubramanian

8/14/2005